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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,398	10/24/2003	Lee A. Core	106586-172 US2	2513

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WILMERHALE/BOSTON
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
GETTMAN, CHRISTINA DANIELLE	
ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
05/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/693,398	CORE, LEE A.	
	Examiner	Art Unit	
	CHRISTINA D. GETTMAN	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,13-18,20,21 and 26-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,13-18,20,21 and 26-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/21/2008,02/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21, 2008, has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (U.S. Patent No. 5,318,588). Horzweski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with a layer with first and second types of sections varying in a circumferential direction and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the conduit being an introducer sheath or a catheter (obvious variations of one another), and a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see

bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 13-16, 20-21, 32, 37, and 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (U.S. Patent No. 5,318,588) in view of Leschinsky (U.S. Patent No. 6,346,092). Horzweski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the inner layer being discontinuous by means of a slit (see ref. 13) and the outer layer being continuous (see Fig. 1B), the conduit being an introducer sheath or a catheter (obvious variations of one another), a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it, and a method of using the device (see Fig. 2A-2F). Horzewski et al. do not disclose a conduit having an inner layer that is non-overlapping. Leschinsky teaches a layer that has slots (ref. 80, Fig. 3A) for the purpose of allowing the end (ref. 70, Fig. 3B) to expand. Leschinsky

shows that it is possible to make a layer that has slots therein that will expand to a second diameter to allow for the passage of another device therethrough. The same concept can be applied to the device of Horzewski et al. because the inner layer would still have the ability to expand if the two ends (ref. 13) were initially side-by-side and then opened to a further diameter. Therefore, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer being non-overlapping, as taught by Leschinsky, in order to allow the conduit to expand radially as a medical device is passed through it. Although there are multiple slots in ref. 70, it would be obvious to make only one slot, ref. 80. Also, Leschinsky is obvious and is combinable with Horzewski because the inner layer of Horzewski is providing for the expansion of the conduit, which ref. 70 is doing in Leschinsky. The combination of Horzewski and Leschinsky also disclose a conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 below).

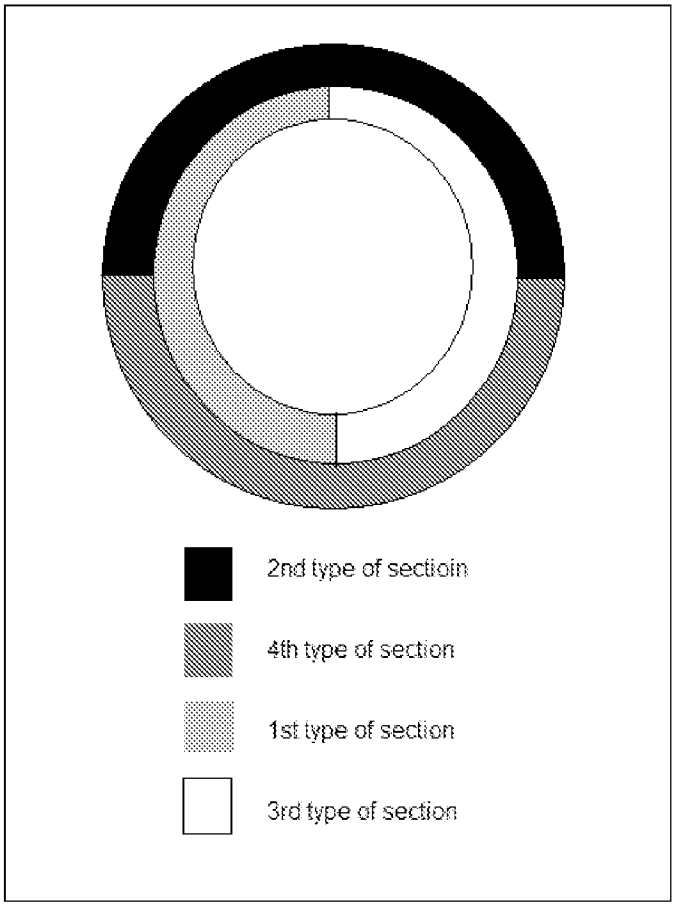

Figure 1. Diagram showing separation of section with the combination of Horzweski and Leschinsky. The 2nd type of section is adjacent to the 1st and 3rd types of section. The 1st and 3rd sections have the same elasticity and the 2nd and 4th sections have the same elasticity.

Claims 40-41 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. as applied to claims 39 and 38. Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a

lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen. Howzeski et al. also disclose a conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 above).

Claims 7-11, 17-18, 33-36, and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. and Leschinsky as applied to claims 4, 16, 1, 23, 19, 32, 39 and 38. Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. The other geometric formations are obvious variation of having a slit and/or an overlapping section that would obtain the same results of expanding the inner layer of the conduit. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The

expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. and Leschinsky with a different geometric formation of the inner layer of the conduit and with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen.

Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. in view of Leschinsky and further in view of Querns et al. (U.S. Patent No. 5,944,691). Horzewski et al. disclose an introducer sheath/catheter having two layers that are bonded to one another, the inner layer being discontinuous by means of a slit (ref. 13) and the outer layer being continuous, and the inner layer having means for allowing its diameter to expand. Howzeski et al. do not disclose a conduit having an inner layer that is non-overlapping. Leschinsky teaches a layer that has slots (ref. 80, Fig. 3A) for the purpose of allowing the end (ref. 70, Fig. 3B) to expand. Therefore, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer being non-overlapping in order to allow the conduit to expand radially as a medical device is passed through it. Although there are multiple slots in ref. 70, it would be obvious to make only one slot, ref. 80. Also, Leschinsky is obvious and is combinable with Horzewski because the inner layer of Horzewski is providing for the expansion of the conduit, which ref. 70 is doing in Leschinsky. Horzewski et al. and Leschinsky do not disclose a method of how the sheath/catheter is formed. Querns et al. teach the method of co-extrusion (col. 3, line 43-54) for the

purpose of forming a two-layered sheath/catheter. It is also an obvious well-known variation to use a method of dipping, as is taught by Conway et al. (U.S. Patent No. 5,906,575; col. 1, lines 54-67), instead of co-extrusion to form the sheath/catheter. Therefore, it would have been obvious to have made the sheath/catheter by either co-extrusion or dipping, as taught by Querns et al., in order to form a two-layered sheath/catheter.

Response to Arguments

Applicant's arguments filed February 21, 2008, have been fully considered but they are not persuasive. Applicant argues that Horzewski lacks at least one layer with first and second type of sections varying in a circumferential direction. Applicant further argues that the elastic sections do not comprise resilient material. Applicant argues that neither Horzewski, nor any of the other references, disclose at least one layer with third and fourth types of sections. Applicant argues that Leschinsky does not teach an inner layer that is discontinuous and non-overlapping. Examiner respectfully disagrees.

As disclosed in the claim limitations, the Applicant does not recited where the at least one layer is in regard to the conduit. The layer could be either with respect to the longitudinal axis of the conduit, with respect to the horizontal axis of conduit, etc. If the layer is a cross-section with respect to the longitudinal axis of the conduit, the cut would have 4 layers, two of which have a higher durometer than the others and the second portion being adjacent to the first and third portions (reciting adjacent does not mean that the two sections need to be directly next to each other). As was discussed in the interview, since there are two materials that are in a circumferential direction, Horzewski

et al. reads on the claims. Leschinsky does teach a discontinous layer with layers that do no overlap one another. It is also not disclosed by the Applicant how providing a non-overlapping layer would have more of an advantage than having an overlapping layer. The two types of layers could still obtain the same expansion radius, if need be. Also, the Applicant does not disclose any advantage to choosing a design of two layers versus one layer with alternating materials in a circumferential direction. The two designs, again, could still expand to the same diameter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 4:30 pm (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina D Gettman/
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